Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Food Safety and Applied Nutrition (CFSAN)
Office of the Center Director (OCD)
Chief Critical Foods Officer

Application Period: March 27, 2023 – May 10, 2023

Area of Consideration: United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Chief Critical Foods Officer

Series: 0601 or 0602

Location(s): College Park, MD

Salary: Starting at $177,123 (0601 series); $210,000 for (0602 series)

Work Schedule: Full Time

Full Performance Band Level: Band F

Cures Band(s): Band F

Travel Requirements: Up to 10%

Bargaining Unit: 8888, Non-Bargaining

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

This position is being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of this authority. Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

Introduction

The Food and Drug Administration (FDA or Agency) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective.

The Center for Food Safety and Applied Nutrition (CFSAN) has the principal responsibility for planning, developing, and administering policies and programs for protecting and promoting

the public health by ensuring that the nation's food supply is safe, secure, sanitary, wholesome, and truthfully and otherwise properly labeled, and that cosmetic products are safe and truthfully and otherwise properly labeled. CFSAN's public health mission also includes implementing initiatives to reduce the rates of nutrition-related risk factors for chronic disease; optimizing health through improved nutrition; fostering the development of healthier foods; and ensuring that consumers have access to accurate and useful information to make healthy food choices.

CFSAN's programs are national in scope and effect, and its activities directly affect and heavily impact upon multi-billion-dollar industries, in addition to protecting the public health of hundreds of millions of American consumers.
The 2023 Consolidated Appropriations Act Omnibus, Subtitle D, included a subsection dedicated to Infant Formula. Specifically, section (b) of this subsection, "Office of Critical Foods", states:

> "(1) IN GENERAL —The Secretary shall establish within the Center for Food Safety and Applied Nutrition an office to be known as the Office of Critical Foods. The Secretary shall appoint a Director to lead such Office; and
> (2) DUTIES —The Office of Critical Foods shall be responsible for oversight, coordination, and facilitation of activities related to critical foods, as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)(2)."

Congress was clear in the Omnibus language that creating an Office of Critical Foods is intended to raise the profile of infant formula.

The Chief Officer for Critical Foods reports to the CFSAN director and will play a leadership role in establishing the Office of Critical Foods. The Office of Critical Foods will have responsibility for the oversight, coordination, and facilitation of activities related to critical foods, the definition of which includes infant formula and medical foods. A defining feature that makes infant formula and medical foods critical is that they frequently serve as a sole source of nutrition for vulnerable populations, including for many populations who cannot tolerate any substitute, such as infants with rare inborn errors of metabolism.

As recently announced [FDA Provides Update on Proposed Human Foods Program and Office of Regulatory Affairs Restructuring | FDA], CFSAN, FDA's Office of Food Policy and Response, as well as certain functions of FDA's Office of Regulatory Affairs are being unified into a newly envisioned organization called the Human Foods Program. This position, as well as the Office of Critical Foods, will be realigned to the Human Foods Program.

Duties/Responsibilities

- This position serves as principal advisor to the CFSAN Director on issues related to critical foods, which include infant formula and medical foods. Provides oversight and leadership direction for all programs and activities associated with infant formula and

medical foods. This includes development of regulatory policies and strategic initiatives as well as scientific evaluations to support regulations and policies; review of compliance and enforcement actions; and follow-up related to adverse events.

- In concert with the director, Office of Nutrition and Food Labeling (ONFL), provides oversight, leadership, and policy direction to a multidisciplinary cadre of medical and nutrition experts that review new infant formula notifications and reformulations to ensure that products meet the critical nutrition needs of infants.

- Provides oversight, leadership, and policy direction to staff charged with keeping abreast of supply chain issues that may affect these critical products.

- In concert with the ONFL Director, collaborates with food program leadership to identify long-range strategic needs, and to develop plans, strategies, policies, program content, direction, priorities, and goals to ensure that objectives are accomplished in critical foods program.

- Reviews study results and offers recommendations including interpreting clinical data and performing additional analysis of data submitted for critical food products.

- Collaborates and maintains active engagement with stakeholder and scientific professional groups and associations groups to keep abreast of current issues, new product formulations, and technology advances that are being made to the composition of infant formula.

- Promotes and ensures collaboration with consumer, public health, and industry stakeholder organizations and represents FDA in conferences, meetings, and discussions with industry representatives, the scientific and academic communities, and national and international scientific and health professional organizations and groups.

- Represents the Agency in meetings and conferences and establishes and maintains effective relationships with White House officials (e.g., the Domestic Policy Council and National Economic Council), top level FDA and HHS officials, national/international industry representatives, members of Congress, counterparts from other Federal, State, and local government agencies, foreign government representatives, academia, consumer and other groups to secure, exchange and provide information concerning policy, science, regulatory, and innovation issues applicable to critical foods.

- Advises Center leadership of potential and emerging scientific, policy, and regulatory legal issues related to infant formula and medical food and proposes appropriate program responses. Issues are identified through a broad personal knowledge and comprehensive understanding of the full range of scientific, technical, and regulatory policies, programs and procedures. Initiates actions to develop and agree upon new

policies, procedures, and practices requiring interaction among Center Offices, other FDA organizations, and other Federal agencies.

- Oversees and directs the medical science generally; this knowledge is typified by completion of an approved residence program supplemented by the incumbent's medical training and clinical experience. The incumbent is licensed to practice medicine in the United States, and is additionally board certified, with a mastery of advanced medical theories, practices, and technologies related to medical science and food/nutrition.

- Provides leadership in shaping short and long-range program goals and understanding of CFSAN's responsibilities for developing and enforcing standards and regulations to protect the consumer. Evaluates the Center's overall efforts and activities and identifies significant weaknesses or problems that may exist and then develops initiatives to ensure their resolution.

- Represents the office and Center before other FDA organizations, government agencies, State and local governments, industry, academia, consumer organizations, Congress, and national and international organizations, and the scientific community.

- Keeps fully abreast of crucial and precedent-setting issues under review within the Office, Center, and FDA in area of emphasis.

- Coordinates and provides interpretation and guidance on regulatory issues related to complex, medical and policy issues.

- Reviews and/or develops guidance documents, regulations, statutory proposals, and other documents related to critical food and provides scientific and technical input.

- Identifies and assesses emerging, standing, complex, or precedent-setting issues affecting the procedures, policies, activities, or resources of the Center.

- Provides guidance to and mentors junior staff members to expand their knowledge and application of FDA scientific and regulatory policies.

- Generates new hypotheses and develops new concepts, methods, and strategies for obtaining and using data on the major medical and health risks associated with critical foods; provides medical and epidemiological expertise in the design and implementation of complex studies.

- Collaborates with other CFSAN and FDA scientists in the design of public health programs, to understand and incorporate the medical aspects in an integrated approach to disease or injury prevention.

- Partners with other government agencies and private organizations to accomplish program objectives. Develops and presents workshops and seminars and represents CFSAN at conferences and meetings sponsored by other government agencies, private organizations, and professional associations.

- Leads reviews of a wide range of critical food product evidence to determine utility for education/outreach, policy, and regulatory activities.

- Reviews study results and offers recommendations including interpreting clinical data and performing additional analysis of data submitted for critical foods.

- May be assigned similar work in other regulated product areas based on the Center's business needs.

Supervisory Responsibilities: The incumbent of this position is directly responsible to, and functions under the broad administrative direction of the CFSAN director. Incumbent is expected to work with an exceptional degree of independence and initiative to reach conclusions and solve problems. Technical advice and recommendations are normally accepted without significant changes. Work is reviewed for accomplishment of broad objectives.

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959, must be registered with the Selective Service.
- One year supervisory probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation/Security Clearance is required. All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.

Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
    a. ***Qualified*** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.
    b. ***Outstanding*** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

Education Requirement:
General Health Scientist Series, 0601

Degree: Bachelor or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Physician Series, 0602

Degree: Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent from a school in the United States or Canada. This degree must have been accredited by the Council on Medical Education of the American Medical Association; Association of American Medical Colleges; Liaison Committee on Medical Education; Commission on Osteopathic College Accreditation of the American Osteopathic Association, or an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the U.S. Evidence of equivalency to accredited schools in the U.S. is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates, a fifth pathway certificate for Americans who complete premedical education in the U.S. and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination.

For more information please see OPM Occupational Series Qualification Requirements

Professional Experience:

- Strong background in pediatric/neonatal clinical nutrition, endocrinology, and/or gastroenterology with senior technical and policy experience. Backgrounds in areas relevant to leading a public health program for infants will be considered.
- Knowledge of the Federal authorities, policies, scientific and regulatory programs as they relate to human foods.
- Talent for building partnerships and coalitions with stakeholders in public and private arenas.
- Demonstrated leadership experience directing a public health, scientific, or regulatory organization.
- Experience in establishing decision-making frameworks that balance public health, legal, regulatory, scientific, and policy considerations.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current FDA employee, you are not exempt from transcript requirements.

FOREIGN EDUCATION: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. For more information about this requirement, please visit the U.S. Department of Education website for Foreign Education Evaluation.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.

Ethics Clearance Requirements

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information, please visit the FDA Ethics web page: https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity

Equal Employment Opportunity Policy

The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service, or other non-merit factor. Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation

Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis. A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits. Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when: An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job. An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis. Learn more about disability employment and reasonable accommodations or how to contact an agency.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

How to Apply

Applications will be accepted from all qualified internal and external applicants. Please send letter of interest addressing your experience in the major duties and responsibilities of the position, SF-50 for current federal employees only, transcript (with foreign credentials evaluation, if applicable) to CFSANExecutiveRecruitment@fda.hhs.gov by May 10, 2023. For questions, please contact CFSANExecutiveRecruitment@fda.hhs.gov.

Please reference Job Reference ID: "***OCD Critical Foods Officer"***

Announcement Contact

For questions regarding this Cures position, please contact
CFSANExecutiveRecruitment@fda.hhs.gov

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FDA is an equal opportunity employer.